UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK Hon. Robert Kugler **Plaintiffs' Reply in Further Support of Their Motion for Class Certification of Consumer Economic Loss Claims**

PLAINTIFFS' REPLY IN FURTHER SUPPORT OF THEIR MOTION FOR CLASS CERTIFICATION OF CONSUMER ECONOMIC LOSS CLAIMS

TABLE OF CONTENTS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

Cases

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

TABLE OF AUTHORITIES
(continued)

Page

Statutes

Rules

Treatises

I. INTRODUCTION

> "*An omnibus class certification motion provides flexibility for structuring different trial plans without sacrificing the preclusive effects of a comprehensive certification decision. Any Defendant-specific issues related to certification could still be addressed in this context…[S]hould certification be granted, Plaintiffs could still seek to sever a specific subclass or issue class for a discrete trial. An omnibus motion would thus increase efficiency while maximizing flexibility*."
>
> –Defendants' Executive Committee, March 9, 2020 (ECF 393)

Two years ago, Plaintiffs proposed the filing of a series of discrete motions for class certification, each seeking to certify a narrowed class of consumers that purchased a particular Manufacturer Defendant's VCDs. ECF 392. Defendants forcibly opposed, arguing that a single "omnibus motion" was the most efficient, flexible approach, recognizing that severing out defendants and subclasses could be used to efficiently implement trials in practice. The Court agreed and Plaintiffs dutifully filed their instant omnibus motion, on behalf of all Consumer EL Plaintiffs (as did TPP and Medical Monitoring Plaintiffs).

Defendants now cynically mischaracterize and accuse Plaintiffs of inviting "chaos" with a single "mega-trial" when that is demonstrably not what Plaintiffs requested. Defs.' Br. at 64, 69. The seed the Defendants planted two years ago bears no fruit for them now.

First, Defendants do not dispute that Plaintiffs satisfy many of Rule 23(a)'s criteria. Defendants also ignore nearly all of Rule 23(b)(3)'s factors (relating to superiority of a class, etc.), except their overstated manageability concerns.

Second, a trial or series of related trials by defendant or defendant groups will be the most manageable option. Courts do not examine manageability in a vacuum, but rather *as compared to* the other options. Here, the alternative would be the true chaos and inefficiency: thousands of redundant individual claims risking contrary results. This Court has a host of trial management tools at its disposal to address the purported manageability concerns here.

Third, Defendants' litany of factual assertions is of no consequence. Every fact they argue—from their purported ignorance about NDMA/NDEA formation, to their professed regulatory diligence—is a common one. That disputed facts may need to be resolved at trial is hardly a bar to certification. Indeed, Defendants' own experts underscore the predominance of common fact questions here; they admit their opinions apply to all class members equally.

Fourth, Defendants' pushback on Plaintiffs' and Dr. Conti's economic damages analysis fares no better. Dr. Conti reliably applies a methodology that has been approved by prior courts and fits the facts and theories in this case. Plaintiffs' damage approach itself presents predominating common questions, as Dr. Conti's method to calculate damages would be the same whether a class were comprised of one person or many thousands.

Fifth, Defendants also are off-base about the impact of multiple states' laws in play here. Informed by this Court's and the Special Master's prior rulings, Plaintiffs thoughtfully limited the proposed subclasses to just a few theories, under the laws of very discrete subsets of states, for which no material differences in law exist.

Finally, Defendants' terse arguments about ascertainability and administrative feasibility are as unconvincing as they are perfunctory. Consumer class members are readily identifiable from the wealth of detailed pharmacy data robustly maintained throughout the industry. Class notice and an opportunity to opt out prior to trial will protect all litigants' rights and can be accomplished in an administratively feasible way.

For these reasons, as well as those set forth in Plaintiffs' opening papers, the Court should certify the proposed Consumer EL Plaintiff class and subclasses.

II. LAW AND ARGUMENT

A. Defendants Do Not Dispute That Plaintiffs Satisfy Many Rule 23 Criteria

1. Defendants Do Not Dispute That Many Rule 23(a) Criteria Are Met

Defendants do not contest that Consumer EL Class Members are sufficiently numerous or the adequacy of proposed Class Counsel. *See* Fed. R. Civ. P. 23(a)(1) & (4). Defendants nominally challenge Consumer EL Plaintiffs' adequacy only to the extent that this criterion merges with the commonality and typicality criteria (*see* Defs.' Br. at 20-21), or because of purported state law differences (*id.* at 63). They do not identify any disabling conflict or idiosyncratic issue with respect to any Consumer EL Plaintiff; nor do they identify any affirmative defense so unique to a particular Plaintiff that they cannot serve as a class representative. While Defendants mention "commonality," they do not dispute that this criterion is "a low threshold" that simply requires a single common question of law or fact. *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 164 (3d Cir. 2001). Finally, as noted *infra* Part II.A.2, Defendants do not contest three of the four factors demonstrating that class treatment is superior to any alternatives.

2. Defendants Do Not Challenge Many Rule 23(b)(3) Criteria

Defendants do not dispute many of the factors enunciated in the superiority analysis of Rule 23(b)(4). Indeed, as Defendants concede: there is no other litigation more progressed than that here, or that it is extremely desirable to concentrate all claims in this forum (an MDL transferee court). This is especially true given the alternative to class treatment is thousands upon thousands of small, individual claims brought in countless jurisdictions throughout the country guaranteed to overburden the judicial system and result in conflicting decisions. Instead, Defendants solely focus on the fourth consideration, "the likely difficulties in managing a class action."

B. Plaintiffs' Proposal Does Not Pose Insurmountable Manageability Concerns

Defendants are bound by what they told this Court two years ago: that an omnibus class

certification motion "would [] increase efficiency while maximizing flexibility … [to] structure different trial plans" that "[a]ny Defendant specific issues related to certification could still be addressed in this context" and that the Court can always "sever a specific subclass or issue class or a discrete trial." ECF 393 at 3. This Court has ample case management tools to efficiently and fairly usher a certified class and subclasses through trial or transfer/remand, including the advancement of discrete groupings or subclasses by defendant, state(s), claims, or issues ahead of the remainder of the class, as necessary. Manageability is not assessed in a vacuum; class treatment must be weighed against the alternative. Here, that alternative is thousands of repetitious individual litigations. And the Court has already demonstrated manageability in guiding the massive fact and expert discovery to date.

1. Plaintiffs' Proposed Class and Subclasses Are Manageable

Consumer EL Plaintiffs essentially proposed three overarching classes, one for each level of the supply chain (Manufacturer, Wholesaler, and Retail Pharmacy). *See* ECF 1747-1. Each EL Consumer class has the same customary class exclusions. Moreover, the three overarching classes satisfy Rule 23. Each class is objectively defined by the following:

(i) **type of claim** (i.e., express and implied warranties, fraud, consumer protection statutes, unjust enrichment);
(ii) **type of party** (i.e., manufacturer, wholesaler, or retailer);
(iii) **geography** (i.e., individuals from certain states only);
(iv) **time** (i.e., the period for which adulterated VCDs were on the market, January 1, 2012 through November 10, 2021),
(v) **type of injury** (i.e., economic loss); and
(vi) **type of relief** (i.e., recoupment of amounts paid).

This is precisely how the judiciary advises such classes to be defined. *See* Ex. 201 (*Managing Related Proposed Class Actions*). Plaintiffs could have stopped here[1] and still satisfied Rule 23.

[1] For example, an overarching class definition of "All persons in X state that paid any amount of

However, Consumer EL Plaintiffs went even further than this standard and took pains to demonstrate to the Court how the overarching classes can be broken down into more discrete, equally certifiable pieces. The Court need not "settle on any particular solution at the same time that it certifie[s] the class," and refusing to do so does not mean "the litigation [will be] unmanageable." *In re Cmty. Bank of N. Va. Mortg. Lending Pracs. Litig.*, 795 F.3d 380, 410 (3d Cir. 2015). This is because "Rule 23(d) vests in the Court substantial discretion to enter orders, subsequent to the Order Certifying the Class that will follow, to manage the class." *Id.* (internal quotation marks omitted).

Thus, Defendants' fearmongering over a "mega-trial" involving "93 different consumer subclasses…[and] 428 distinct varieties of valsartan" (an exaggeration in any event), *see* Defs.' Br. at 1, is far-fetched and immaterial. Defendants' imagined fears (which they invited with their request made over two years ago) amount to nothing more than "tag-along argument[s]" that are "premature" and "speculative," and which do not defeat class certification. *In re Cmty. Bank*, 795 F.3d at 409-10.

2. Many Manageability Tools Are at the Court's Disposal

Failure to certify a class because it *might* be unmanageable is "disfavored and should be the exception rather than the rule." *In re Visa Check/MasterMoney Antitrust Litig.*, 280 F.3d 124, 140 (2d Cir. 2001) (Sotomayor, J.) (internal quotations and citation omitted).[2] This is because Rule 23 empowers district courts "to devise imaginative solutions created by the presence in a class action litigation" of certain issues, and district courts have a "number of management tools

money for a VCD for personal/household use that was made, distributed, or sold by one or more [manufacturers *or* retailers *or* wholesalers] between January 1, 2012 and November 10, 2021."

[2] *See also, e.g.*, *In re Syngenta AG MIR 162 Corn Litig.*, 2016 WL 5371856, at *12 & n.11 (D. Kan. Sept. 26, 2016) ("'… courts within at least seven circuits have held that there is a presumption against dismissing a class action on manageability grounds or that such dismissals are disfavored.'" (quoting 2 *Newberg on Class Actions* § 4:72 & n.7)).

available" to manage class actions. *Id.* at 141.

The *Manual for Complex Litigation (Fourth)* further summarizes the variety of tools courts employ to manage class action and/or multi-party litigation. For instance, the Court "can limit the number of witnesses, require depositions to be summarized, call for the presentation of the direct evidence by written statements, and use other techniques."[3] Or, a "court may consider trying common issues first, preserving individual issues for later determination," try a "test case" first while holding other cases or claims in abeyance, or employ summary jury trials.[4] Other methods abound, including an inter-circuit assignment of the transferee judge (here, Your Honor) to preside over the trial of any case or claims remanded to a transferor court,[5] trying only certain claims to verdict but asking the jury to render advisory opinions on other claims,[6] or having the Special Master serve as a trial master to hear or make recommendations on certain facts or issues.[7]

Several courts have successfully employed these tools to effectively manage, try, and ultimately resolve multistate classes consolidated in MDLs. The *Albuterol* MDL similarly involved contaminated drugs, and the district court there certified multistate classes and ordered a bifurcated class trial. *See In re Copley Pharm., Inc.*, 158 F.R.D. 485, 493 (D. Wyo. 1994). The court noted "[t]he injuries alleged by these named Plaintiffs are not the most complex," and found

---

[3] *Manual for Complex Litigation (Fourth)* § 21.5; *see, e.g.*, *City & Cty. of San Francisco v. Purdue Pharma LP*, No. 3:18-cv-07591 (N.D. Cal.) (ordering that in lieu of direct examination at trial the witnesses would provide affidavits).

[4] *Manual for Complex Litigation (Fourth)* § 21.5; *see, e.g.*, *Sharp v. Coopers & Lybrand*, 457 F. Supp. 879, 896 (E.D. Pa. 1978), *aff'd*, 649 F.2d 175, 192 (3d Cir. 1981) (bifurcating issues common to the class from individual issues of reliance and damages).

[5] *Manual for Complex Litigation (Fourth)* § 20.132; *see, e.g.*, *Sanofi Ltr. re Notice Seeking Intercircuit Assignment, In re EpiPen Mktg., Sales Practices, & Antitrust Litig.*, No. 17-md-2785 (D. Kan. June 25, 2020) (ECF 2117) (outlining the process for the court to request an inter-circuit assignment under Section 292(d) to the District of New Jersey).

[6] *See, e.g.*, *Moitoso v. FMR LLC*, 410 F. Supp. 3d 320, 322 (D. Mass. 2019).

[7] *See, e.g.*, Fed. R. Civ. P. 53(a)(1)(B); *Chisolm v. TranSouth Fin. Corp.*, 194 F.R.D. 538 (E.D. Va. 2000) (appointing special master to assist in trial of class action).

that "a single jury in a unified trial" made sense for the defendant's liability for the contaminated drugs purchased by class members. *Id.* at 490, 492. The *Copley* court later declined[8] a request to decertify and re-affirmed the manageability of a bifurcated, multi-state class trial. *Id*. at 456.

The Third Circuit, in fact, has upheld class certification in multi-product, multi-defendant litigation much more sprawling than this one. *In re Asbestos Sch. Litig.*, 789 F.2d 996 (3d Cir. 1986) (en banc) (affirming Rule 23(b)(3) certification in expansive litigation involving series of class claims ~14,000 schools nationwide, asserting various state common law claims against ~50 defendants operating at all levels of supply chain). As the Third Circuit held in *In re Asbestos*:

> The use of the class action device appears to offer some hope of reducing the expenditure of time and money needed to resolve the common issues which are of substantial importance. As the *Jenkins* court commented, "It is difficult to imagine that class jury findings on the class questions will not significantly advance the resolution of the underlying hundreds of cases."

789 F.2d at 1010 (quoting in part *Jenkins v. Raymark Indus. Inc.*, 782 F.2d 468, 472-73 (5th Cir. 1996)). The issues here are much narrower than those in *Asbestos*. But as in *Asbestos*, each putative class member's claim will turn on the same evidence of Defendants' actual or constructive knowledge, etc., all of which will be proven by the same documents and witnesses.

Another example touted as a success by the Federal Judicial Center is the *In re Motor Fuel Temperature Sales Practices Litigation*. That MDL, much like this one, "was an industry-wide, multi-defendant MDL proceeding involving proposed classes in twenty-six states." Ex. 201 at 10. After streamlining early motions practice and discovery, the Court certified and prioritized proposed classes based on particular states or defendants. *See, e.g.*, *In re Motor Fuel Temp. Sales*

[8] The *Copley* court identified the common issues that are similar here, and proposed a succinct, two-phase trial plan. *Id.* at 468-69. It also was undeterred by potential state law variances, holding that: "the Court is not intimidated by the parade of horribles presented by the Defendant." *Id.* at 465-66; *see also id.* at 469 ("… the application of common issues concerning the other twenty-five states should conserve judicial and litigation resources for all involved.")

Pracs. Litig., 271 F.R.D. 221, 238-239 (D. Kan. 2010) (first certifying class of Kansas residents against all defendants); *In re Motor Fuel Temp. Sales Pracs. Litig.*, 279 F.R.D. 598 (D. Kan. 2012) (denying request to decertify Kansas class). Later, after some defendants settled and others did not, at Defendant Chevron's request, the court severed and stayed the claims brought by California residents against all defendants except Chevron. The Court then proceeded to certify a class of California residents' claims against Chevron, endorsed a bifurcated class trial plan, and remanded the then-certified California class back to a transferor court.[9] *In re Motor Fuel Temp. Sales Pracs. Litig.*, 292 F.R.D. 652 (D. Kan. 2013).

As *Motor Fuel* illustrates, the mere fact that an MDL transferee court receives multi-state class claims, against multiple defendants, does not in itself render class certification unmanageable. Quite the contrary, the reason the JPML transfers related class actions to a single transferee court as here is precisely to tackle, on a unified basis, all pre-trial matters including class certification. Were it true that a request to certify multistate classes in related class actions would be *ipso facto* unmanageable, then the very efficiencies underlying MDL consolidation would never be achievable.[10] Nothing stops this Court, after the certified class claims are crystallized following summary judgment, from proceeding with a 'test' or 'bellwether' subclass to trial, for instance a

[9] Chevron argued, as Defendants here, that a class would be unmanageable "because it would require the Court to examine individual purchasing behavior of each putative class member[.]" *Id.* at 673. The court disagreed, finding that "Plaintiffs will not need to prove individual circumstances regarding each class member, but can show injury by classwide proof." *Id.*

[10] Yet another example is the *In re FCA US LLC Monostable Electronic Gearshift Litigation*. There, related class actions seeking economic damages were consolidated by the JPML, and 39 named plaintiffs from 23 different states sought class certification. 334 F.R.D. 96 (E.D. Mich. 2019). Unlike here, the plaintiffs there did not do the "heavy lifting of analyzing state by state and claim by claim," but the Court nonetheless certified an issues class. *Id.* at 108-117. The court recognized that straightforward special verdict forms could be used as appropriate and ultimately the multi-state notice program was approved, trial notice was disseminated, and the certified class is approaching trial. *See* Ex. 202 (proposed special jury verdict forms); Ex. 203 (notice plan).

subclass involving only one manufacturer and class members from only one state.

The breadth of management tools available, and their successful use as catalogued above, are more than adequate to address Defendants' boogeyman rhetoric about *Lexecon*, venue, and personal jurisdiction issues. Defendants cite nothing that prevents this Court from certifying the Consumer EL Classes and Subclasses, adjudicating summary judgment and pretrial *motions in limine*, and then severing and remanding cases to transferee courts as appropriate.[11] Defendants' implied threat that they may withhold *Lexecon* waivers (*see* Defs.' Br. at 70) is a hollow one. For one, at least a dozen if not more Defendants are at home in New Jersey, including the domestic entity of every VCD manufacturer except Mylan. ECF 1708. These Defendants also are named in multiple original class actions filed in this District,[12] as well as in the operative master complaints. Nothing stops this Court from trying any claims against these Defendants.[13]

3. Plaintiffs Are Not Required to Submit an Exhaustive "Trial Plan" At This Stage

Defendants misstate the need for an exhaustive, set-in-stone trial plan right now. A trial plan is not an all-inclusive script for every single facet of eventual trial(s) (nor could it be at this stage with dispositive and pre-trial motions still forthcoming). In practice, trial plans tend to be "relatively informal documents, essentially a short description of the party's vision of how the case will unfold. Trial plans are provisional and often evolve during litigation." 2 *Newberg on Class*

---

[11] *In re FCA Monostable*, 340 F.R.D. 251, 254 (E.D. Mich. 2022) (court "unquestionably has full authority to try all claims in the matters that were direct-filed in the Eastern District of Michigan and reassigned as companion proceedings to be consolidated with the MDL").

[12] *See Erwin v. Prinston Pharm. Inc., et al*., Case No. 18-cv-13447 (D.N.J*)*, *O'Neill v. Solco Healthcare U.S. Inc., et al*., No. 18-cv-14840 (D.N.J.); *Stimma v. Torrent Pharma Inc.*, *et al.,* Case No. 18-cv-14318 (D.N.J.).

[13] To the extent class claims against an outlier Defendant cannot be tried in this District for whatever reason (withholding of *Lexecon* waiver, personal jurisdiction, etc.), the Court can sever class claims, direct the Clerk to open a new matter for those claims, and transfer that matter accordingly. *See* Fed. R. Civ. P. 21; *In re Seroquel Prods. Liab. Litig.*, 2006 WL 3929707 (S.D. Fla. Dec. 22, 2006).

Actions § 4:79. As a matter of law, trial plans are not even required at the Rule 23 stage.[14]

Plaintiffs' three-phase trial plan aligns with those frequently entered in other multistate, multi-defendant consolidated actions and class actions.[15] For instance, the court in *Turner v. Murphy Oil USA, Inc.* certified a class in 27 consolidated class actions. 234 F.R.D. 597 (E.D. La. 2006). The trial plan was only two pages long, and also proposed three phases.[16] The *Turner* court nonetheless found the plan sufficient.[17]

It is axiomatic that trial plans must be flexible in order to evolve as a litigation progresses. If, for instance, the class claims are narrowed or Plaintiffs prevail on a motion for partial summary judgment before trial, or if the Court chooses to try a particular subclass first (instead of all claims, on behalf of all subclasses, against all Defendants at the same time), the trial plan will be modified to accommodate these rulings. Plaintiffs' proposed three-stage trial plan is flexible enough to accommodate such modifications. Defendants themselves touted this "flexibility" (their words) two years ago. ECF 393. Flexibility must be expected at this stage, given that not a single Defendant has even filed an answer to the Master Complaints, and the parameters of the claims and defenses are in flux. For these reasons, other courts required proposed trial plans only after

[14] *See, e.g.*, *Wachtel ex rel. Jesse v. Guardian Life Ins. Co. of Am.*, 453 F.3d 179, 186, n.7 (3d Cir. 2006) (trial plans not "mandatory"); *see also, e.g.*, *Chamberlain v. Ford Motor Co.*, 402 F.3d 952, 961, n.4 (9th Cir. 2005) (per curium) ("Nothing in the Advisory Committee Notes suggests grafting a requirement for a trial plan onto the rule.").

[15] *See, e.g.*, Ex. 204 (three-phase plan submitted in *In re Juul Labs, Inc. Marketing, Sales Practices, and Products Liability Litigation*, No. 19-md-02913 (N.D. Cal) (see also tentative certification order at ECF 2600); *Suchanek v. Sturm Foods*, Inc., 2018 WL 6617106, at *16 (S.D. Ill. July 3, 2018) (succinct trial plan involving two separate jury trials, first trial to be bifurcated).

[16] 2 *Newberg on Class Actions* § 4:79 (reproducing and discussing plan adopted by Judge Fallon at class certification stage).

[17] *Turner*, 234 F.R.D. at 606 (citing *Mullen v. Treasure Chest Casino, LLC*, 186 F.3d 620, 628 (7th Cir. 1999) (affirming bifurcated plan and citing instances of bifurcated class action trials)).

certifying classes and subclasses.[18] Allowing for a proposed trial plan to occur after summary judgment and motions *in limine* also addresses Defendants' *Lexecon* arguments and purported venue or jurisdictional issues.

C. Defendants' Drummed-Up "Factual Disputes" Do Not Defeat Class Certification

Defendants' eagerness to argue the merits and ultimate liability questions (*see, e.g.*, Defs.' Br. at 10) ("Plaintiffs' [] Allegations Against the Manufacturers Are False"), or for this Court to draw factual inferences favorable to them (*id.* at 2-18), has no place at the Rule 23 stage. Defendants' factual arguments underscore how common facts predominate in this litigation.

1. Defendants' Arguments Highlight the Predominance of Common Questions

First, Defendants' lengthy recitation of manufacturer-centric facts simply confirms the predominance of common fact and legal questions. Questions of how the contamination occurred, when and how each Manufacturer Defendant discovered NDMA/NDEA contamination, the impurity levels, and recall history (Defs.' Br. at 2-9), are all common questions of fact. Every single "fact" argued by Defendants would be used, over and over again, by every single class member were they to pursue individual trials. More generally, factual and legal questions that turn on Defendants' own conduct are all inquiries that will be subject to common adjudication.

Second, purported variations in Consumer EL Plaintiffs' exposure to NDMA/NDEA (*see* Defs.' Br. at 8-10), has zero bearing on this ***economic loss*** consumer class certification motion. The dosage of VCDs purchased, the amount of VCDs ingested, and how much NDMA/NDEA were ingested by consumers (*id.* at 12-14) does not change the fact that each class member *paid for* these economically worthless drugs, and suffered economic harm at the point of sale.

Third, whether or not Defendants' adulterated VCDs were medically effective in treating

[18] *See, e.g.*, *Espenscheid v. DirectSat USA, LLC*, 705 F.3d 770, 773, 775 (7th Cir. 2013) (requesting submission of trial plans for bifurcated trial proceedings after class certification).

hypertension (Defs.' Br. at 14-15) is irrelevant, as this Court has already determined. Each Class Representative testified that they would not have bought the adulterated VCDs had they known the truth (assuming they even could have bought an adulterated drug, which is illegal to sell in the first place); that given the choice they would not buy adulterated VCDs; that they never obtained refunds for their out-of-pocket costs; or that they seek full out-of-pocket economic damages for the adulterated VCDs they and other class members purchased.[19]

Fourth, that class members might have paid varying amounts for VCDs (Defs.' Br. at 15) is immaterial and does not defeat class certification.[20] Similarly, Defendants' attempt to conflate this case as being about "428 distinct varieties of valsartan" (Defs.' Br. at 1) is not well-taken. For one, by definition, *all* of Defendants' VCDs were supposed to be "the same" as the respective RLD including in dosage. More saliently, variety in product strength (i.e., dosage) or package size does not impact class certification.[21] This includes purported variations in reimbursements or potential refunds (*see* Defs.' Br. at 15). It is black letter law that aggregate damages are sufficient for Rule 23, and that a defense of potential offsets is itself a common question.[22] And, it is undisputed that data, if reliable, exists for any refunds provided by any pharmacy or manufacturer such refund can be incorporated within the damages model. *See also infra* Part II.D.4.

---

[19] Exs. 205-245. This includes the one plaintiff incorrectly contended by Defendants as believing she seeks damages for bodily injury (*see* Defs.' Br. at 15).

[20] *See, e.g.*, *In re Suboxone (Buprenorphine Hydrochloride & Nalaxone) Antitrust Litig.*, 421 F. Supp. 3d 12, 63 (E.D. Pa. 2019); *see also, e.g.*, *In re Processed Egg Prods. Antitrust Litig.*, 312 F.R.D. 171, 180 (E.D. Pa. 2015) ("Differing purchasing methods and prices do not necessarily defeat a finding of typicality and adequacy").

[21] *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 599 (3d Cir. 2012) (finding that a plaintiff who purchases only one type of product, in a suit involving many products, "satisfies the typicality requirement" if there are uniform misrepresentations).

[22] *Allen v. Holiday Universal*, 249 F.R.D. 166, 194-95 (E.D. Pa. 2008) (certifying class even if offsets are present) *see also, e.g., Korolshteyn v. Costco Wholesale Corp.*, 2017 WL 1020391, at *8 (S.D. Cal. Mar. 16, 2017) (to decline certification because of potential refunds might allow defendant's return policy to effectively immunize them "from any suit seeking restitution").

2. Defendants' Own Experts Confirm the Predominance of Common Questions

Defendants' own class certification experts admitted that their opinions are common to all class members. For instance, a Teva-specific expert, Timothy Anderson, admits that [redacted] Other defense class experts testified similarly.[24] One defense expert even agreed [redacted]

D. Plaintiffs Present a Common, Reliable Methodology for Calculating Classwide Damages

Defendants' outlandish assertion that Plaintiffs "have no [damages] model" (Defs.' Br. at 56) could not be more wrong. Plaintiffs and their healthcare economist, Dr. Reni Conti, present a reliable, court-tested method for estimating aggregate damages on a classwide basis.

1. Plaintiffs Reliably Estimate Damages on a Classwide Basis

Defendants do not deny that, at class certification, a plaintiff may satisfy the predominance requirement by using an aggregate damages model that calculates classwide harm, "even if more individualized determinations are needed later to allocate damages among class members." *In re Suboxone (Buprenorphine Hydrochlorine & Naloxone) Antitrust. Litig.*, 967 F.3d 264, 271 (3d Cir. 2020). Dr. Conti uses reputable third-party data from IQVIA to calculate the classwide aggregate economic harm at the point-of-sale. ECF 1748-1 ("Conti Decl.") at ¶ 9, *see also* Conti Supplemental Declaration ("Conti Supp. Decl."). She further segments her damages estimates by Defendant (each defendant, be they manufacturer, wholesaler, or retailer), by state, and by theory.

[23] Ex. 246 (Anderson Tr.) at 20:15 – 24:15.
[24] *See, e.g.*, Ex. 247 (Baertschi Tr.) at 92:4 – 93:12; Ex. 248 (Williams Tr.) at 25:11-18.
[25] Ex. 248 (Williams Tr.) at 25:11-18.

Id. at Attach. E. Her model is flexible enough to account for modifications that may arise at a subsequent stage in this litigation, e.g., if a bellwether class trial first proceeds against only certain defendants, or for class members in only certain states under only certain theories. *Id.* at ¶ 11. Plaintiffs adequately demonstrate their "theory of injury and damages is provable and measurable by an aggregate model relying on class-wide data." *In re Suboxone*, 967 F.3d at 272.

2. Plaintiffs' Aggregate Damages Model Fits Their Theories and the Facts

Defendants misapply *Comcast Corp. v. Behrend*, 569 U.S. 27, 37-38 (2013). *See* Defs.' Br. at 56-57. *Comcast* merely requires that a plaintiff's aggregate damages model "match[] a viable theory of liability." *In re Suboxone*, 967 F.3d at 270. No so-called "*Comcast* problem" exists here because the proposed damages model fits the theories of liability and facts of this case.

Plaintiffs allege they purchased adulterated VCDs, entitling them to damages under various states' laws. To estimate damages for Defendants' misconduct under those states' laws, Dr. Conti opines that there is no "legitimate supply curve" for adulterated drugs because federal law (and analogous state laws) prohibit the sale of adulterated drugs. *See, e.g.*, 21 U.S.C. §§ 331, 351. This is consistent with the undisputed record in this case, wherein every Retail Pharmacy and Wholesaler Defendant's corporate designee testified [redacted][26]

Defendants' own experts concede that adulterated drugs cannot be sold and are economically worthless. For example, Dr. Bottorff agreed that [redacted][27] Another defense expert, Mr. Timothy Kosty, goes farther. He agrees that

[26] *See* Exs. 252-264 ([redacted]).
[27] *See, e.g.*, Ex. 265 (Bottorff Tr.) 242:12; Ex. 249 (Kosty Tr.) at 120:23 – 121:8, 122:7 – 123:21.

[redacted] Defense expert, Dr. Punam Keller, [redacted].[32] Dr. Conti's damages model fits the facts and legal theories, and satisfies *Comcast*.

3. Courts Routinely Rely on Damages Models Just Like Dr. Conti's Here

Dr. Conti's aggregate damages model has already been found to be reliable by another court in this Circuit. In *Blue Cross Blue Shield Association v. GlaxoSmithKline LLC*, 2019 WL 4751883 (E.D. Pa. Sept. 30, 2019) ("*BCBS*"), thirty-eight TPPs sought to recoup monies paid for drugs that were manufactured out of cGMP compliance. The *BCBS* plaintiffs argued, as Plaintiffs argue here, that "the adulterated drugs were worthless and had they known of the adulteration they would not have" paid for them. *Id.*

The *BCBS* defendants sought to exclude Dr. Conti's opinions for the same reasons Defendants do here. Plaintiffs will discuss more fully in their forthcoming Dr. Conti *Daubert*

[28] Ex. 249 (Kosty Tr.) at 120:23 – 121:8, 122:7 – 123:21.
[29] *Id.* at 121:10 – 122:5, 155:16 – 156:17, 157:15.
[30] *Id.* at 125:21 – 127:21.
[31] *Id.* at 144:16 – 145:3l; *see* Ex. 268 (Sheinin Tr.) at 221:13-222:2, 224:16-225:21, 247:3-13.
[32] Ex. 266 (Keller Tr.) at 197:22 – 198:19.

opposition, but the short of it is that Judge Sánchez found Dr. Conti's opinions reliable, rejected arguments identical to those Defendants make here, and found that Dr. Conti's "damages calculation is not flawed for not factoring in any rebates Plaintiffs may have received for the At-Issue Drugs or any therapeutic alternatives they may have had to cover as a result of discontinuing coverage for the At-Issue Drugs." *BCBS*, 2019 WL 4751883, at *9.

Other courts routinely grant class certification and approve point-of-sale (or purchase-price or full-refund) damages models in cases where plaintiffs allege that a product is worthless, both whether it is contaminated[33] or otherwise safe but was not what it purported to be.[34] Defendants' pair of cases are of no help to them. The first case turned on the individualized implications of the learned intermediary doctrine in a products liability-type case, because the at-issue products remained on the market.[35] No one argues that doctrine here, because VCDs were all recalled (and should have been recalled earlier). The other case involved products liability failure-to-warn type claims involving a branded (not generic) drug; did not involve any adulteration (contamination or cGMP failures); and sought class treatment for consumers who suffered *actual physical injuries*.[36] This class case does not allege products liability claims; seeks only economic damages; and

[33] *See, e.g., Steroid Hormone Prod. Cases*, 181 Cal. App. 4th 145, 150-159 (2010) (approving full refund damages model where supplements were contaminated finding "in this case [Plaintiff] does not put valuation at issue when he alleges that he bought a product that was illegal to sell or possess."); *see also Debernardis v. IQ Formulations, Inc.*, 942 F.3d 1076, 1088 (11th Cir. 2019).
[34] *See, e.g., In re Amla Litig.*, 282 F. Supp. 3d 751, 756, 767 (S.D.N.Y. 2017); *Krueger v. Wyeth, Inc.*, 2011 WL 897144, at *2 (S.D. Cal. Mar. 30, 2011) (approving full refund model despite evidence that doctors continued prescribing drug and that plaintiff *continued taking the drug* even after becoming aware of health risks); *Rikos v. Procter & Gamble Co.*, 799 F.3d 497, 524 (6th Cir. 2015) ("Whether purchasers were nevertheless satisfied with Align does not affect the propriety of a full-refund damages model.").
[35] *See Andren v. Alere, Inc.*, 2018 WL 1920179, at *4 (S.D. Cal. Apr. 24, 2018) ("It is now not disputed that the learned intermediary doctrine applies to the six subclass states based on a failure to warn.").
[36] *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61 (S.D.N.Y. 2002).

involves generics that were adulterated.

4. Potential "Individual Damages Issues" Do Not Preclude Class Certification

Individual damages issues do not defeat class certification. "[D]ifferences among the class members concerning the precise damages they suffered . . . are of no consequence in determining whether there are common questions concerning liability." *In re Suboxone*, 967 F.3d at 272. The Third Circuit has indicated that denying class certification based on a finding of individualized damages would "amount[] to an abuse of discretion." *Neale v. Volvo Cars of N. Am., LLC*, 794 F.3d 353, 375 (3d Cir. 2015).

Thus, it matters not whether some class members paid different prices for VCDs. *See e.g.*, *id.*; *Sampson v. USAA*, 2022 WL 1415652, at *7 (W.D. La. May 3, 2022). Further, the purported "therapeutic value" received by each class member is irrelevant because all class members were deprived the "***entire*** benefit of their bargain" by having purchased an economically worthless drug, *Debernardis*, 942 F.3d at 1088 (emphasis added), and because the economic harm occurred at point-of-sale as this Court has determined.[37] To the extent Defendants obliquely imply certain states' laws might allow different measures of damages (Defs.' Br. at 59), such concern is illusory because Plaintiffs break out subclasses by state, the Court has yet to hear or decide summary judgment arguments that will sharpen the claims and their elements including damages, and the Court may instruct on and properly mold damages as appropriate at trial.[38] *See, e.g.*, *McAdam v.*

[37] *See, e.g.*, ECF 775 at 19-20 ("… contaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, were never bargained for."); *BCBS v. GlaxoSmithKline LLC*, 417 F. Supp. 3d 531, 557 (whether "Plaintiffs' damages calculation [by Dr. Conti] is improper because Plaintiffs should have discounted any therapeutic value they received from the noncompliant drugs [] is necessarily a credibility dispute between the parties' experts"); *see also* Conti Decl. at ¶ 11.

[38] Plaintiffs cannot be expected to shadowbox now against defenses Defendants *might* raise at summary judgment and prior to service of any answer.

Dean Witter Reynolds, Inc., 896 F.2d 750, 777 (3d Cir. 1990) (finding no error in court's molding jury verdict as to damages).

Equally, Defendants' throw-away line about potential refunds (*see* Defs.' Br. at 16) is a non-starter. Again, offsets, refunds, and other potential after-the-fact damages adjustments do not defeat class certification because such assertions go to the *extent* of damages, not the fact of liability and occurrence of injury. *See supra* Part II.C.1. Further, refunds can be allocated during the claims administration process.[39]

Relatedly, as to Defendants' footnote suggesting two class representatives (Messrs. Nelson and Kessinger) did not pay for VCDs or received a "free replacement" (*see* Defs.' Br. at 15-16), the factual record actually indicates otherwise. [40] Notably, Defendants do *not* seek to disqualify either Messrs. Nelson or Kessinger as inadequate class representatives on this fallacious basis.

5. Plaintiffs and Dr. Conti Reliably Estimate Unjust Enrichment Damages

Defendants contend that classwide modeling of unjust enrichment damages (as to Wholesaler and Retail Pharmacy Defendants only) is "troublesome" without "factor[ing] in the cost of goods sold" (*see* Defs.' Br. at 38 & n.115) and that "[t]he varying value that each Plaintiff received" (Wholesaler Br. at 21-23) is disabling to certification. Not so.

First, because unjust enrichment focuses on the conduct of the defendant, Defendants' own

[39] [redacted]

[40] Plaintiff Nelson purchased a single prescription of adulterated VCDs manufactured by Teva on [redacted] laintiff Kessinger's testimony aligns with his CVS prescriptions records [redacted] Ex. 251 (Kessinger Tr.) at 72:15 – 74:5); Ex. 273 (Kessinger Depo. Ex. 6).

cases recognize the claim is "well-suited for class treatment." *In re Thalomid & Revlimid Antitrust Litig.*, 2018 WL 6573118 (D.N.J. Oct. 30, 2018).

Second, "varying value" is just a rehash of Defendants' faulty "diminution in value" argument. Plaintiffs and Dr. Conti properly model point-of-sale damages, which Defendants' own experts agree is an appropriate measure if injury occurs at point of sale.[41] Even if permissible under unjust enrichment law, proving a defendant's costs to offset their profits is *Defendants'* burden, not Plaintiffs' burden.[42]

Moreover Dr. Conti *does* take into consideration Retail Pharmacy Defendants' costs. As she described at her deposition, every drug dispensed by a pharmacy includes a factor intended to compensate for the cost of dispensing that drug.[43] As to Wholesaler Defendants' costs (or to the extent Retail Pharmacy Defendants assert their costs are different than what Dr. Conti has modeled), again, proving same is Defendants' burden, not Plaintiffs' burden.[44]

Finally, inasmuch as Defendants fault Plaintiffs for not using Defendants' actual cost data, Defendants gloss over that this is an issue of their own making as Plaintiffs explicitly sought cost information from Wholesaler and Retail Pharmacy Defendants, this was opposed, the discovery

[41] *See* ECF 2046 (Pls.' Mtn to Preclude Stiroh); ECF 2048 (Pls.' Mtn to Preclude Kosty); ECF 2044 (Pls.'s Mot to Preclude Lambert); ECF 2041 (Pls.' Mtn to Preclude Keller).
[42] *See, e.g.*, *Rexall Sundown, Inc. v. Perrigo Co.*, 707 F. Supp. 3d 357, 359 (E.D.N.Y. 2010); *Lockheed Martin Corp. v. L-3 Commc'ns Integrated Sys, L.P.*, 2009 WL 8435667, at *3 (N.D. Ga. Apr. 9, 2009).
[43] Conti Decl. at ¶ 52, 54.
[44] To the extent some Defendants argue they keep aggregated not drug-by-drug cost accountings (*see* Wholesaler Br. at 22), it has been the law for nearly a century that the Supreme Court "has sustained recovery of the full amount of defendant's profits where his own wrongful action has made it impossible for the plaintiff to show in what proportions he and the defendant have contributed to the profits." *Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 265 (1946). If Defendants wish to argue different costs diminish the class's recovery, they may try to do so. But that fact does not defeat class certification. More significantly, any such cost-based argument is itself a common question amenable to classwide proof.

denied (without prejudice), and the data can be produced if needed.[45]

E. Defendants' Critiques of Plaintiffs' State Law Groupings and Claim-Specific Individualized Issues Are Without Merit

Defendants present an inaccurate picture of Third Circuit law on state law groupings. Their contention that "nuances" or lack of identicality preclude state law groupings (Defs.' Br. at 22) is unsupported by Third Circuit law. Indeed, they solely rely on a single abrogated out-of-circuit case.[46] Third Circuit law directs a more practical, liberal approach to state law groupings.

This circuit's pragmatic approach stems, in part, from *In re Asbestos*, wherein the Third Circuit agreed with a district court that the plaintiffs made a "creditable showing" that state law groupings did not present "insuperable obstacles" to trial management. 789 F.2d at 1010. *In re Asbestos* explicitly held that "variations in the rights and remedies available to injured class members under the various laws of the fifty states [do] not defeat commonality and predominance." *Id.* Never then nor since has the Third Circuit held, let alone intimidated, that minor "nuances" defeat certification or that material identicality is required. *Sullivan v. DB Investments, Inc.*, 667 F.3d 273, 301 (3d Cir. 2011) (en banc) (citing *In re Warfarin*, 391 F.3d 516, 529 (3d Cir. 2004)).

Instead, the Third Circuit instructs courts to decide whether the groupings: (1) are based on "predictable patterns" within a "broad constellation" of laws; (2) present "insuperable"

---

[45] Plaintiffs will not revisit the extensive history of this particular discovery dispute. Plaintiffs aggressively sought cost data, and the Wholesaler and Retail Pharmacy Defendants vigorously fought the request for "competitive" business reasons. Magistrate Judge Schneider denied Plaintiffs' request without prejudice, but left open the possibility that Plaintiffs may be able to renew their request. ECF 507. Defendants cannot withhold from discovery information sought by Plaintiffs, only then to fault Plaintiffs for not having the very data Defendants refused to produce. *See Ware v. Riley*, 587 Fed. App'x 705, 711-12 (3d Cir. Oct. 8, 2014) (affirming order preventing party from arguing at trial evidence that party failed to produce during discovery).

[46] *Klay v. Humana, Inc.*, 382 F.3d 1241 (11th Cir. 2004), *abrogation recognized by*, *Cherry v. Dometic Corp.*, 986 F.3d 196 (11th Cir. 2021) (vacating order that denied multi-state class certification). Defendants are incorrect that the Third Circuit "adopted" *Klay* in *Grandalski v. Quest Diagnostics Inc.*, 767 F.3d 175, 183-84 (3d Cir. 2004). The Third Circuit merely noted that, unlike here, *Klay* did not have "virtually any [] analysis" of states' laws. *Id.* 767 F.3d at 183.

obstacles that render the class litigation unmanageable; and (3) present a "workable solution." *In re Warfarin*, 391 F.3d at 529; *Grandalski*, 767 F.3d at 183-84.

Plaintiffs hew exactly to this precedent. Nowhere do Plaintiffs blindly seek 'nationwide certification' under the laws of all fifty states (and two territories). *See* Defs.' Br. at 1. Rather, Plaintiffs seek to certify subclasses grouped based on the lack of conflict of laws between discrete subsets of states' laws, while taking into account issues that are subject to common evidence. Nor are Plaintiffs painting a choice-of-law analysis on a blank canvas. This Court has twice engaged in a thorough analysis to weed out unviable state-law claims and define the theories of liability under those claims, once at the motion to dismiss stage (*see, e.g.*, ECF 728, 775, 818, 838, 1019), and again in overruling Defendants' objections to the Special Master's order (ECF 1614) permitting Plaintiffs to file the now-operative Amended Master Complaints (*see* ECF 1994). Plaintiffs' discrete state law groupings account for this Court's and the Special Master's prior rulings. Plaintiffs' careful analysis shows the absence of material conflicts of law, setting this matter apart from those relied on by Defendants, in most of which choice-of-law issues were neither broached nor adequately presented by the plaintiffs.[47]

1. Defendants' Reliance on the Denial of Proposed Nationwide Class Cases Is Irrelevant to This Court's Analysis

The vast majority of the decisions relied on by the Defendants involved simple requests for nationwide certification of all state laws' claims, instead of the thoughtful state-by-state analysis

[47] Notably, a "false conflict" means that no choice-of-law analysis is necessary because there are no material differences between states' laws based on the facts at hand. *See, e.g.*, *Lucker Mfg., A Unit of Amclyde Eng'g Prods., Inc. v. Home Ins. Co.*, 23 F.3d 808, 813 (3d Cir. 1994). Only if an actual conflict arises should the Court then engage in a full choice-of-law analysis. *Id.* That analysis still may result in the application of certain states' laws that *avoids* any actual conflict. Were the Court to find that an actual conflict of law exists in a particular instance, the appropriate course would be to direct additional briefing and decide which state's law might apply.

presented by Plaintiffs here for each claim.[48]

2. Plaintiffs' Subclass Groups Do Not Present "Insuperable" Obstacles

Defendants spitball purported variations in state law, but fail to prove, let alone discuss, how these variations are "insuperable." Insuperable obstacles are more than minor technical difficulties or semantical differences in statutory or judicial language. An insuperable obstacle is one that is *impossible* to overcome. The test is *not* whether a class becomes slightly more complex from a trial management prospective – it must be rendered unmanageable with "intractable," unfixable problems. *Grandalski*, 767 F.3d at 180. Defendants ignore these twin considerations under Third Circuit law. It must be *impossible* and *unmanageable* to rely on Plaintiffs' subgroups. The unattainability of perfection does not defeat class certification.[49]

3. Plaintiffs Show That Groupings Are a "Workable Solution"

To determine if movant satisfied its burden of presenting a "workable solution," the Third Circuit suggests a court ask whether a party shows: (1) their groupings would apply to the facts and issues presented by their case; (2) how the jury could be charged in a coherent manner relative to the proposed groupings; and (3) enough information or analysis to justify the proposed

[48] In *Lewis Tree Serv., Inc. v. Lucent Techs. Inc.*, the court denied class certification for fraud claims in a "single nationwide class." 211 F.R.D. 228, 236 (S.D.N.Y. 2002). In *Agostino v. Quest Diagnostics Inc.*, the court found that the plaintiffs did not meet their burden of establishing that variations among state laws of common fraud can be managed efficiently in a single, nationwide class action. 256 F.R.D. 437 (D.N.J. 2009). The same can be said for the other cases Defendants relied upon, including *In re Ford Motor Co. Vehicle Paint Litig., Darisse v. Nest Labs, Inc.*, and *Five-Hour Energy Marketing & Sales Practices Litig.* – not one of these cases involved a state-law subclass grouping designed by the plaintiffs to make the litigation manageable.

[49] For sake of argument, Plaintiffs amend their state law groupings per Defendants' critiques. This alone shows that issues may be clarified and streamlined before trial on the papers, and that "nuances" will not hold a jury "hostage" as Defendants prognosticate. Moreover, the Court itself can amend groupings. *See* 3 William B. Rubinstein, *Newberg on Class Actions* § 7:27 (5th ed. June 2020 update) (noting that "several circuits have held that a court should alter the class definition in lieu of rejecting class certification, if possible"). Plaintiffs' redlined and amended class definitions are found at Ex. 274 and Ex. 275 (redline), and the groupings are found at Ex. 276.

groupings (e.g., charts setting forth comprehensive analyses of the various states' laws potentially applicable to their common law claims). *Grandalski*, 767 F.3d at 183-84. Defendants do not fully address any of these informal factors while Plaintiffs satisfy each as part of their extensive analysis

Specifically, Plaintiffs: (1) fully briefed how their subclass groupings would apply to the facts and issues in this case (*see* ECF 1748, pp. 77-106); (2) explained in their opening papers how the jury could be charged relative to the proposed groupings (*id.*); and (3) provided comprehensive information and analysis justifying the proposed groupings, including charts setting forth comprehensive analyses of the various states' laws potentially applicable to their common law claims. ECF 1748-5, 1748-6. Plaintiffs' efforts as to each theory on which they seek certification are discussed below.

4. Defendants' Materiality- or Reliance-Related Individualized Issue Arguments Are Foreclosed by the Common Undisputed Facts and the Court's Rulings to Date

Defendants posit that individualized questions will predominate over Plaintiffs' claims where some kind of materiality or reliance element is present ("basis of the bargain" for express warranties, "merchantability" for implied warranties, or "materiality" or "reliance" for fraud and consumer protection claims). This, however, is specious in light of Plaintiffs' theories and common proof, as well as the Court's explicit rulings to date.

For express warranty claims, Defendants argue that selling "valsartan" that was represented to be FDA-approved and therapeutically equivalent to the RLD was not part of the "basis of the bargain" for some consumers. Aside from the factual absurdity that any consumer may have not understood they were purchasing a prescription pharmaceutical containing "valsartan" the Court has flatly rejected the argument.[50]

[50] As this Court found, "Plaintiffs did not have to 'perceive' the package labelling or insert in order to create a benefit of the bargain. All they had to know was they were buying a generic drug that

For implied warranty "merchantability" and fraud/consumer protection "materiality" Defendants' apparent speculative argument is, at best, that contamination with highly potent and dangerous carcinogens is not something that may be material to consumers and may not make their VCDs non-merchantable under some states' laws. At worst, it is an attempt to inject general medical causation into these economic loss claims when it has no place.

In the context of tightly regulated prescription pharmaceuticals, Defendants' VCDs were non-merchantable based on the common and established factual record and no matter how any particular state law defines the standard. Defendants' VCDs were adulterated and illegally sold, 21 U.S.C. §§ 331(a) & 351, and were subject to recall based on common evidence, meaning they were ***literally*** non-merchantable in every state (and as evidenced by their removal from the market). Indeed, a non-defendant generic finished dose manufacturer has sued its API supplier because the API was "unmerchantable" due to NDMA contamination. *See* Ex. 277 at ¶ 32. Defendants here seek to hold consumers to a more stringent standard of merchantability than their own sophisticated corporate peers hold each other in industry business dealings.

As to the fraud and consumer protection materiality and reliance standards, those are likewise met conclusively for similar reasons. A manufacturer's representation or omission is material "if a reasonable consumer 'would attach importance to its existence or nonexistence in determining his choice of action in the transaction in question.' Alleged defects that create

---

contained valsartan because the very name 'valsartan' or 'valsartan-containing' constituted itself an express warranty that what plaintiffs were purchasing was the chemical equivalent of the Orange Book pharmaceutical." ECF 775, at 14. In addition, "by securing FDA approval to market their generic VCDs in the United States as an Orange Book listed drug, the Manufacturing Defendants represented their VCDs were therapeutically equivalent to the reference listed drug. Similarly, by presenting consumers with an FDA approved label, the Manufacturing Defendants represented their VCDs were consistent with the safety, quality, purity, identity, and strength characteristics reflected in that label." *Id.*

'unreasonable safety risks' are considered material." *Daniel v. Ford Motor Co.*, 806 F.3d 1217, 1225-26 (9th Cir. 2015) (citations omitted); *McDermott v. Cummins, Inc.*, 2016 WL 3287335, at *6 (D.N.J. June 7, 2016) (same); *Kearney v. Bayerische Motoren Werke Aktiengesellschaft*, 2018 WL 4144683, at *12 (D.N.J. Aug. 29, 2018) (same). Specifically, the Eleventh Circuit found in *Debernardis* that adulteration of dietary supplements resulting in their having been illegally sold was a material defect resulting in economic worthlessness. This Court has already agreed with that analysis. ECF 775 at 20 ("[T]his court is persuaded by *Debernardis* ….").

Reliance is likewise conclusively established as a matter of undisputed common evidence. The very naming of a drug as valsartan and selling it as FDA-approved therapeutic equivalents to the RLD induced reliance (i.e., consumers "had no choice but to rely" in this Court's own words) when they were prescribed the drug and bought it as a medication for their high blood pressure.[51]

Common evidence will establish the falsity of the material representations. Here, Plaintiffs will demonstrate via common evidence that Defendants' pervasive cGMP violations in their manufacturing processes[52] led to contamination of their valsartan with genotoxic impurities that they admit are probable human carcinogens. When this was disclosed, every manufacturer recalled the contaminated valsartan because it was adulterated and presented an unreasonable risk to humans.[53] The presence of genotoxic probable human carcinogens NDMA and NDEA further

[51] As this Court found, "The Mfrs' very naming of the drug as valsartan or valsartan-containing amounted to a warranty [or representation] on which plaintiffs ***had no choice but to 'rely'*** when they were prescribed the drug and bought it[.]" ECF 775, at 14 (emphasis added).

[52] ZHP's own cGMP expert, Mr. David Chesney, admitted that [redacted] *See* Ex. 271 (Chesney Tr.) at 114:12-115:3, 329:9-331:16. Common evidence will show that other defendants similarly [redacted]. *See, e.g.*, ECF 1748-4 (Quick Decl.).

[53] Ex. 272 [redacted] (emphasis added).

establish the materiality of Defendants' misconduct because the "[a]lleged defects … create 'unreasonable safety risks.'" *Daniel*, 806 F.3d at 1225-26. That is why the drugs were recalled.

Product defects that compromise their safe use are *ipso facto* material, and even in the particular states identified by Defendants (California,[54] Delaware,[55] Louisiana,[56] Maryland[57]) with supposedly different merchantability standards for implied warranty, Defendants do not articulate how any of these standards would be meaningful on the common facts of this case. *Grandalski*, 767 F.3d at 183-84.

More generally, Defendants' attempt to engraft general causation onto the EL class actions in order to create an additional proof hurdle fails because Plaintiffs have already cleared that hurdle. Moreover, the EL plaintiffs are quite unlike a "plaintiff in a **product liability action** [who] must prove both general and specific causation." *In re Johnson & Johnson Talcum Powder Prods. Liab. Litig.*, 509 F. Supp. 3d 116, 192 n.52, 197 (D.N.J. 2020) (emphasis added). By definition, whether or not physical injury occurred is irrelevant to economic loss, and there is no requirement to prove specific or general medical causation. Defendants' references to medical monitoring law are similarly inapposite. *See* Defs.' Br. at 13-14. And the Court has already decided, as a general legal proposition at the Rule 12 stage (ECF 775) and as a preliminary factual finding on competing general causation expert reports (ECF 1958 & 1974), that the NDMA/NDEA in the amounts

---

[54] Under **California** law, defects are material if they pose "safety concerns." *See Avedisian v. Mercedes-Benz USA, LLC*, 43 F. Supp. 3d 1071, 1078 (C.D. Cal. 2014) (collecting cases).

[55] Defendants cite no Delaware law regarding manufacturing defects rendering a product non-merchantable, they only cite to design defect law.

[56] Defendants' citation to **Louisiana** redhibition law is similarly unavailing because Louisiana is grouped as a standalone state subclass. Nevertheless, Defendants fail to articulate how the slightly different formulation of the standard would make any difference on the facts of this case.

[57] Defendants fail to explain how one formulation of **Maryland's** merchantability standard creates any kind of conflict with other state law on the facts of this litigation. In addition, Maryland courts have also articulated a "reasonably safe" standard in some contexts for merchantability. *Lloyd v. Gen. Motors Corp.*, 916 A.2d 257, 285 (Md. 2007).

present in Defendants' VCDs pose a significant risk of cancer.

Defendants' pair of cases on this score are of no help. *Harris v. Pfizer Inc.* involved a branded drug (not generics, as here), alleged diminished value (not worthlessness, as here), and had no discussion about adulteration due to persistent cGMP violations, variation from compendia, or contamination creating "significant risks" because the complaint there (unlike here) lacked such allegations.[58] Defendants' other case, which they claim suggests "materiality is a highly consumer-specific inquiry," did not concern the particular context of adulterated prescription drugs, or an unreasonable safety risk of the type here.[59]

5. Plaintiffs' Legal Theories and State Groupings, the Common Factual Evidence, and the Court's Rulings Foreclose Any Individualized Liability Issues

Defendants make several arguments regarding supposed individualized liability issues that will arise under Plaintiffs' claims. Defs.' Br. at 41-61. Plaintiffs' theories and proof for each claim, however, are based on common evidence supported by the Court's rulings; indeed, most of the individualized liability issues raised by Defendants have been previously rejected by the Court.

a. Express Warranties

Despite arguing "important legal variations" in express warranty law, Defendants are scant on details. Indeed, Defendants do not even identify with specificity the state' laws Plaintiffs supposedly got wrong on privity and pre-suit notice (Defs.' Br. at 24-25). Defendants also:

---

[58] 2022 WL 488410 (S.D.N.Y. Feb. 16, 2022). The *Harris* court mostly based its decision on a single FDA announcement. To derive "merchantability" or immateriality for fraud-based claims from that FDA statement alone, without any kind of factual record, was simply an incorrect result, and as the *Harris* court recognized, likely contrary to this Court's more reasoned decisions. (ECF 775, at 20 (finding dangerously contaminated drugs non-merchantable as a matter of law "regardless [of whether they] actually achieved the medical purpose of lowering blood pressure").) For example, the *Harris* decision completely omits discussions of adulteration, and federal law rendering illegal the sale of adulterated drugs. 21 U.S.C. §§ 331(a) & 351. In fact, the word appears nowhere in the opinion. Goods that are quite literally illegal to sell, and recalled for same, are classically non-merchantable (a common question).

[59] *Clark v. Prudential Ins. Co. of Am.*, 940 F. Supp. 2d 186, 193 (D.N.J. 2013).

(i) daydream up interpretative maxims and misapply the *Erie* doctrine; (ii) discuss defenses that have zero application to this litigation (e.g., statutes of limitation, despite nationwide tolling commencing weeks after the recalls); and (iii) gin up "variations" where none exist (*e.g.*, grossly exaggerating privity and notice issues, or pretending that some states do not allow "zero-value" damages when all states' laws allow reasonable-basis jury awards). Simultaneously, Defendants disregard the law of this case.

First, Defendants concoct a fallacious maxim suggesting where the state's highest court has not spoken on an issue, this court should *automatically* opt for the narrowest interpretation of liability. Defs.' Br. at 22. The Third Circuit instructs otherwise.[60] This Court should not *blindly* opt for the narrowest interpretation that restricts liability, as Defendants suggest, but rather conduct the usual analysis of predicting how the state's highest court would actually rule. Plaintiffs' state law groupings reflect this and the correct *Erie* analysis.

Second, statutes of limitations variations are a non-starter here as to any of the claims because the first class action lawsuits were filed within weeks of the initial recalls in 2018.

Third, purported 'variations" concerning manifestation of defect ignores uncontroverted common evidence that *literally all* of the ZHP, Torrent, Mylan, Teva, and Hetero VCDs during their respective class periods were in fact contaminated with NDMA/NDEA, and all Defendants' VCDs were adulterated due to serious cGMP violations. *See* Pls.' Br. at 9-10 (ZHP), 15 (Mylan), 20-21 (Teva), 26-27 (Torrent), 30 (Hetero), 31 (Aurobindo). The immateriality of "therapeutic value" and classwide reliance being shown are discussed *supra* Parts II.D.4 & II..E.4, respectively.

Fourth, as to privity and express warranties, Defendants agree with Plaintiffs' groupings

[60] *Spence v. ESAB Grp., Inc.*, 623 F.3d 212, 216–17 (3d Cir. 2010) (setting forth careful and informed analysis courts should undertake in predicting state law applications).

for most states (Defs.' Br. App'x F), but nevertheless assert (without actually naming the states) that Plaintiffs got privity wrong in "at last [sic] six states in which privity is required" for express warranty. Defs.' Br. at 24. While unclear, reviewing their Appendix F, Defendants appear to challenge Plaintiffs' express warranty privity analysis as to Arizona;[61] Florida;[62] Kentucky;[63] New York;[64] North Dakota;[65] and Tennessee.[66] As footnoted herein, Defendants are wrong in each instance. Similarly, Defendants assert (without naming the states) that Plaintiffs incorrectly grouped another 15 states as to pre-suit notice requirements. The attempted injection at all of a pre-suit notice dispute on the common facts of this litigation is beyond the pale.[67] Regardless, Defendants' positions regarding pre-suit notice are simply untenable in nearly all the fifteen (15)

[61] *Flory v. Silvercrest Indus., Inc.*, 129 Ariz. 574, 580, 633 P.2d 383, 389 (1981) (holding under **Arizona** law that "[n]o privity of contract [is] required…where the seller is a remote manufacturer).
[62] *Karhu v. Vital Pharm., Inc.*, 2013 WL 4047016, at *6 (S.D. Fla. Aug. 9, 2013) (finding that privity was not required because "express warranties … were contained on the packaging [of the pharmaceutical product]… directed toward the end-purchaser").
[63] *Naiser v. Unilever U.S., Inc.*, 975 F. Supp. 2d 727, 739-40 (W.D. Ky. 2013) ("...an express warranty action can be maintained where alleged written, express warranties were clearly intended for the product's consumers.").
[64] *Mancuso v. RFA Brands, LLC*, 454 F. Supp. 3d 197, 207 (W.D.N.Y. 2020) ("**New York** dispensed with the privity requirement for express warranty claims seeking economic damages").
[65] *Haugen v. Ford Motor Co.*, 219 N.W.2d 462, 466 (N.D. 1974) (holding that under **North Dakota** law "the lack of privity between a buyer and manufacturer is no defense where … product was sold under its trade name, and…placed the product in the stream of trade").
[66] *First Nat. Bank of Louisville v. Brooks Farms*, 821 S.W.2d 925, 929 (Tenn. 1991) (holding under **Tennessee** law that the "manufacturer should be liable in this situation" of express warranty claims arising from "commercial losses resulting from a defectively manufactured product.").
[67] The common factual record is that all Defendants had actual knowledge of their contamination prior to any lawsuit being filed because they all recalled their VCDs and notified their customers as required by law. *See, e.g.* 21 CFR Part 7. Further, all Defendants received *at least* one pre-suit notice letter that set forth all the claims under all the laws of 50 states on behalf of all class members; whatever the substantive notice requirement is under any state's law, the Court may find as a common factual and legal question that this letter alone satisfies the standard. *See* ECF 577-1; Ex. 278.

states identified. In the District of Columbia,[68] Illinois,[69] and Indiana,[70] pre-suit notice is not required and/or is conclusively satisfied when the defendants were all on constructive or, as here, actual notice of the defect (they all recalled the VCDs). In the states of Florida,[71] Hawaii,[72] Minnesota,[73] Missouri,[74] South Carolina,[75] Virginia,[76] and Washington,[77] pre-litigation notice is not required against remote manufacturers and is only required against immediate sellers. Under New Mexico law, consumers simply are not required to provide pre-suit notice at all.[78] In Pennsylvania[79] and Rhode Island,[80] filing of a complaint satisfies any pre-suit notice requirement.

---

[68] *Witherspoon v. Philip Morris Inc.*, 964 F. Supp. 455, 464-65 (D.D.C. 1997) (constructive notice satisfies pre-suit notice requirement under **D.C.** law).
[69] *Connick v. Suzuki Motor Co.*, 174 Ill. 2d 482, 494 (Il. 1996.) (under **Illinois** law, notice not required when there is "actual knowledge").
[70] *Anderson v. Gulf Stream Coach, Inc.*, 662 F.3d 775, 782 (7th Cir. 2011) (under **Indiana** law, the notice requirement is satisfied where the defendant has actual knowledge of the defects).
[71] *PB Prop. Mgmt., Inc. v. Goodman Mfg. Co.*, 2014 WL 12640371, at *3–4 (M.D. Fla. Aug. 14, 2014) ("Plaintiffs are correct in their assertion that notice is required to be given to the seller, not the manufacturer, under **Florida** law.").
[72] Haw. Rev. Stat. § 490:2-607 (pre-litigation notice of defect only required to "seller" under **Hawaii** law).
[73] *Church of the Nativity v. Watpro, Inc.*, 474 N.W.2d 605, 609–610 (Minn.App.1991) (notice need go only to immediate seller under **Minnesota** law).
[74] *Ragland Mills, Inc. v. General Motors Corp.*,763 S.W.2d 357, 361 (Mo. Ct. App. 1989) (in general, buyer required to give notice only to immediate seller under **Missouri** law).
[75] *In re Volkswagen Timing Chain Prod. Liab. Litig.*, 2017 WL 1902160 (D.N.J. May 8, 2017) (finding that under **South Carolina** law, the buyer of a product is only required to provide notice to the seller, and not "the remote manufacturer" of product) (Linares, J.).
[76] *Yates v. Pitman Mfg., Inc.*, 257 Va. 601, 605, 514 S.E.2d 605, 607 (1999) ("We hold, therefore, that only buyers; i.e., those who buy or contract to buy goods from a seller… must give notice.")
[77] **Washington** has a downstream purchaser exception wherein the notice requirement applies only to a buyer's "knowledge of a defect prior to acceptance, and does not apply to downstream purchasers." *Cats v. Monaco RV, LLC*, 2016 WL 5253204, at *4 (W.D. Wash. Sept. 22, 2016).
[78] *In re Santa Fe Nat. Tobacco Co. Mktg. & Sales Pracs. & Prod. Liab. Litig.*, 288 F. Supp. 3d 1087, 1272 (D.N.M. 2017) (finding "that notice should not be required in these suits").
[79] *In re Nexus 6P Prod. Liab. Litig.*, 293 F. Supp. 3d 888, 914 (N.D. Cal. 2018) ("**Pennsylvania** state courts have held that the filing of a complaint may satisfy the notice requirement for a breach of warranty claim).
[80] *In re Abilify (Aripiprazole) Prod. Liab. Litig.*, 2021 WL 1041017, at *5 (N.D. Fla. Feb. 10, 2021) (**Rhode Island** "the filing of the complaint constituted sufficient notice of the breach of the implied warranty.").

b. Implied Warranties

Defendants mount a similarly vague and unavailing challenge to the implied warranty groupings. First, Defendants argue that Plaintiffs have failed to account for state law variations regarding the standard for "merchantability" of their NDMA/NDEA contaminated and adulterated VCDs. Defs.' Br. at 27. This is addressed *supra*.

As for privity and pre-suit notice, Defendants are again flat wrong on their legal characterizations.[81] Defendants incorrectly refer to a few implied warranty states where Plaintiffs supposedly got privity wrong (California,[82] Virginia,[83] and Georgia[84]). As for pre-suit notice, Defendants refer to many of the same states Plaintiffs have already addressed for express warranty pre-suit notice. *See supra,* at Part II.E.5.a. New states where Defendants take issue with Plaintiffs' legal characterizations are incorrect also, and include Iowa,[85] Maine,[86] Massachusetts,[87] and New York.[88]

---

[81] As with express warranties, Plaintiffs are moving the states of **South Dakota** and **Wyoming** to state groupings reflecting that pre-suit notice may be required.

[82] **California** law recognizes an exception to privity in implied warranty claims for pharmaceutical drugs intended for human consumption, which applies both to bodily injury and economic loss claims. *See, e.g., Haley v. Bayer Healthcare Pharms. Inc.*, 2016 WL 10966426, at *3–4 (C.D. Cal. June 9, 2016) (cataloguing cases).

[83] **Virginia** has legislatively abolished privity for claims seeking direct (as opposed to consequential) economic damages. *Gasque v. Mooers Motor Car Co.*, 227 Va. 154, 162, 313 S.E.2d 384, 390 (Va. 1984).

[84] **Georgia** law allows implied warranty claims for economic loss damages where the remote manufacturer has made express warranties to the ultimate consumer. *Lee v. Mylan Inc*., 806 F. Supp. 2d 1320, 1325–26 (M.D. Ga. 2011).

[85] *In re MyFord Touch Consumer Litig.*, 46 F. Supp. 3d 936, 977 (N.D. Cal. 2014) ("Under **Iowa** law, notice to the manufacturer is not required.").

[86] Decisions interpreting **Maine** law have found that pre-suit notice is not necessary when the defendant has constructive notice of the product defect. *Muehlbauer v. Gen. Motors Corp.*, 2008 WL 4542650, at *4 (N.D. Ill. July 22, 2008) (compiling and discussing authorities).

[87] Under **Massachusetts** law, the filing or joining of a complaint is sufficient. *In re Ford Motor Co. E-350 Van Prod. Liab. Litig. (No. II)*, 2010 WL 2813788, at *78 (D.N.J. July 9, 2010), amended, 2011 WL 601279 (D.N.J. Feb. 16, 2011).

[88] **New York** courts and courts interpreting New York law have found that pre-suit notice is not

Plaintiffs' revised state groupings attached hereto also address (for sake of argument only) Retail Pharmacies' assertions about pharmacy implied warranty liability. For claims that have been dismissed and remained so after the Court's reconsideration order (ECF 1994), Plaintiffs simply never included those states in groupings. For the states included, Defendants do not refer to any specifics as to how those state laws vary in any material way. *See* Defs.' Br. at 29.

c. Fraud

Defendants' ambiguous takes on standards of proof, state-of-mind, materiality and reliance (discussed *supra*) for the fraud claims do not rise to the level of meaningful, disabling state-law variations.

Whatever the standard, the proof presented at trial will be the same and any jury can be tasked with sorting out whether that proof meets some or all of the different standards in verdict forms. *Todd v. XOOM Energy Maryland, LLC*, 2020 WL 4784767, at *13 (D. Md. Aug. 18, 2020) (rejecting such an argument "because the underlying factual proof is the same, these differences could be adequately addressed with a verdict form and do not defeat predominance."); *Spencer v. Hartford Fin. Servs. Grp., Inc.*, 256 F.R.D. 284, 301 (D. Conn. 2009).

Second, Defendants claim Plaintiffs misconstrued the scienter requirement for presumably twenty (20) states identified in Defendants' Appendix H. For six (6) these states (D.C., Iowa, Louisiana, North Dakota, Rhode Island, and Virginia), Plaintiffs and Defendants agreed; accordingly there is no dispute. For eight (8) others (Arkansas, California, Idaho, New Hampshire, Nevada, Ohio, South Dakota, Wisconsin), Defendants' *own authorities* in Appendix H support Plaintiffs' groupings; Defendants are being coy, counting even slightly different wording of what is otherwise a similar standard (for example, New Hampshire's standard is "conscious indifference"

---

necessary when the product defect is for products intended for human consumption. *In re Hydroxycut Mktg. & Sales Practices Litig.,* 2010 WL 2839480, at *3 (S.D. Cal. July 20, 2010).

which is legal defined as recklessness). For the remaining states (with the exception of North Carolina and Tennessee, which are reassigned for sake of argument in Plaintiffs' charts), Defendants are just wrong (Alaska,[89] Massachusetts,[90] Illinois,[91] Minnesota[92]).

e. Consumer Protection Statutes

Defendants incorrectly claim that Plaintiffs should have excised states with class action restrictions from their groupings, citing the Supreme Court's *Shady Grove Orthopedic Assocs. v. Allstate Ins. Co.* case, 559 U.S. 393 (2010), which did not contain a such a holding. Judge Rodriguez's thoughtful analysis in *Amato v. Subaru of America* correctly notes that the Third Circuit has explicitly endorsed Justice Scalia's categorical approach to reach a conclusion that "Rule 23, not state law, governs the availability of class action treatment of [state law] claims." 2021 WL 2154976, at *7 (D.N.J. May 27, 2021). This Court should follow *Amato* and the Eleventh Circuit decision cited therein[93] to find that Rule 23 governs federal class action procedure, categorically displacing state law restrictions on consumer protection class actions.

Defendants similarly misstate that Plaintiffs employ a "presumption" of reliance in this litigation. That is inaccurate. Although not even necessary in some states (*e.g.,* New Jersey with affirmative representations), Plaintiffs will *prove* reliance based on common and undisputed facts "conclusively establish[ing]" (the words of the Motion) that every EL class member, in this Court's words, "had no choice" but to rely on Defendants' representations. ECF 775 at 14.

---

[89] *Zeman v. Lufthansa German Airlines*, 699 P.2d 1274, 1285 (Alaska 1985) (**Alaska**).
[90] Under **Massachusetts** law, the claims of common law fraud (which requires actual knowledge) and intentional misrepresentation are merged. *See* Ex. 269 (Massachusetts jury instructions).
[91] *Duran v. Leslie Oldsmobile, Inc.*, 594 N.E.2d 1355 (Ill. App. 1992) (**Illinois** scienter element "that was known or believed by the speaker to be untrue or made in *culpable ignorance of its truth or falsity*" (emphasis added)).
[92] *U.S. Bank N.A. v. Cold Spring Granite Co.*, 802 N.W.2d 363, 373 (Minn. 2011) (**Minnesota** *scienter* element articulated as "made with knowledge of the falsity of the representation or *made without knowing whether it was true or false*" (emphasis added)).
[93] *Lisk v. Lumber One Wood Preserving, LLC*, 792 F.3d 1331 (11th Cir. 2015).

As to what constitutes a deceptive act or practice, Defendants take issue with Plaintiffs' reliance on the FTC Act for grouping purposes, citing *Grandalski*, 767 F.3d 175. In *Grandalski*, it was apparent that the plaintiffs had made little effort to actually justify their groupings, instead merely relying on a "based on the FTC Act" argument without any explanation or application to the facts of the case. *Id.* 767 F.3d at 183. Nevertheless, the Third Circuit did remark that "grouping, in general, may be a permissible approach to nationwide class action litigation" so long as "enough information or analysis" is provided. *Id.* Plaintiffs have demonstrated that FTC guidance defines "deception" in ways that are unquestionably applicable, including but not limited to "failure to meet warranty obligations" or "sales of hazardous or systematically defective products or services without adequate disclosures" under various states' laws. *See* ECF 1748 at 88 & Ex. 192 (FTC Policy Statement defining deception).

For *scienter*, Defendants apparently take issue with Plaintiffs' state law groupings for approximately nine (9) states. With the exception of Louisiana,[94] Defendants are flat wrong as to the remaining states (District of Columbia,[95] Illinois,[96] New Hampshire,[97] North Dakota,[98]

[94] For the sake of argument, Plaintiffs' revised charts move **Louisiana** to the group of intent-required states.

[95] *Beck v. Test Masters Educ. Servs. Inc.*, 994 F. Supp. 2d 90, 93–94 (D.D.C. 2013) (finding that under **D.C.** CPPA, a plaintiff does not have to allege or prove *intentional* misrepresentation or failure to disclose in order to prevail on the claim).

[96] *Chow v. Aegis Mortg. Corp.*, 286 F. Supp. 2d 956, 963 (N.D. Ill. 2003) (find that the "deceptive act and intent requirements can be satisfied by innocent misrepresentations of a defendant.")

[97] *Beer v. Bennett*, 993 A.2d 765, 769 (N.H. 2010) ("We conclude that [in **New Hampshire**] the defendant's reckless disregard for the truth of his statements satisfies the degree of knowledge or intent required by *Kelton*.").

[98] Under **North Dakota**'s Consumer Fraud Act, a plaintiff need only prove that the defendant intended the plaintiff to rely on the statement contended to be deceptive. N.D.C.C. § 51-15-02; *see also DJ Coleman, Inc. v. Nufarm Americas, Inc.*, 693 F. Supp. 2d 1055 (D.N.D. 2010).

Oregon;[99] Kansas;[100] Minnesota;[101] Wisconsin[102]). Finally, Defendants' fleeting assertion that a heightened scienter requirement attaches to consumer protection statute claims brought against pharmacies (Defs.' Br. at 37) is made without any legal citation whatsoever. Even were this true (and it is not), it falls short for the same reasons discussed *supra* Part II.E.3.c (fraud).

f. Unjust Enrichment

Retail Pharmacy Defendants and Wholesaler Defendants' broad attack on unjust enrichment emptily relies on linguistic judo and is ultimately self-defeating. They repeatedly *group states* by reference to the trier of fact's obligation to holistically view all facts: they variously describe the same inquiry as a "balancing test" that includes a "weighing of the equities", a "fact-specific inquiry" that is deliberately "a broad and imprecise" concept rejecting any "formulaic elements" ultimately "left to the court's discretion" based on the "totality of the circumstances" Almost by definition, the Court can group these states together because the trier of fact's responsibility is ultimately the same: to weigh *all* of the circumstances.

In addition, Retailer and Wholesaler Defendants focus on which states require some kind of inequity to be shown. Plaintiffs intend to show this through common and unassailable proof. Virtually every single Retail Pharmacy Defendant and Wholesaler Defendant testified through binding corporate representative testimony that they cannot and do not sell adulterated

---

[99] *Gilberto v. Walgreen Co.*, 2020 WL 1890538, at *2 (D. Or. Apr. 16, 2020) (finding that you only need show that a "Defendant was reckless as required to maintain a class action under **Oregon's** UTPA.").

[100] Defendants' own Appendix I concedes that for the deceptive acts prong of **Kansas** CPA, the standard is "knowingly or with reason to know."

[101] *301 Clifton Place L.L.C. v. 301 Clifton Place Condo. Ass'n*, 783 N.W.2d 551, 563 (**Minn**. Ct. App. 2010) ("Liability does not require that the false statement be intentional. *Meyer v. Dygert,* 156 F. Supp. 2d 1081, 1086 (D.Minn.2001)).

[102] Defendants' own Appendix I concedes that under Wisconsin's CPA, the plaintiff need only prove that the defendant's misrepresentation was made with the intent to induce the purchase at issue.

pharmaceuticals. *See* Exs. 252-264. The unassailable common facts are that (1) Defendants' VCDs were adulterated and therefore illegally sold, *see, e.g.*, 21 U.S.C. §§ 331(a) & 351; and (2) were distributed by and sold to Plaintiffs and Class Members by Retail Pharmacy Defendants (passing through Wholesaler Defendants). Common proof will demonstrate inequitable circumstances based on these binding admissions.

F. Defendants' Ascertainability Arguments Lack Merit

Defendants' *pro forma* ascertainability arguments (Defs. Br. at 71-75) are inconsistent with Third Circuit law and this case's record.[103] To be ascertainable, a class need only be "defined with reference to objective criteria," and there must be an "administratively feasible mechanism for determining whether putative class members fall within the class definition." *Byrd v. Aaron's Inc.*, 784 F.3d 154, 163 (3d Cir. 2015). Defendants do not dispute that Plaintiffs' proposed class and subclass definitions are defined with reference to objective criteria.

As to administrative feasibility,[104] Defendants incorrectly argue that Plaintiffs must identify each and every class member at this stage. The exact opposite is true: a "plaintiff need not 'be able to identify all class members at class certification—instead, a plaintiff need only show that class members ***can*** be identified.'" *City Select Auto Sales Inc. v. BMW Bank of North America Inc.*, 867 F.3d 434, 439 (3d Cir. 2017) (quoting *Byrd*, 784 F.3d at 163) (emphasis original). The Third Circuit reiterated this a few years later in *Hargrove*, in which the Third Circuit reversed a district court that required plaintiffs to "identify the class members at the class certification stage"

[103] It speaks volumes that Defendants did not even file a *Daubert* motion to challenge Ms. Laura Craft and her methodology to identify class members.

[104] Defendants Opposition appears to attempt to inject "administrative feasibility" (part of the ascertainability inquiry) into other aspects of the case including superiority (of which a component is manageability). This is incorrect. *Hargrove*, 974 F.3d at 479; *accord Briseno v. ConAgra Foods, Inc.*, 844 F.3d 1121, 1126-28 (9th Cir. 2017) (stating that Third Circuit "administrative feasibility" requirement is only applicable to provision of notice and ascertainability).

as "too demanding" a standard. *Hargrove v. Sleepy's* LLC, 974 F.3d 467, 470 (3d Cir. 2020). The *Hargrove* court found that the class was ascertainable even though there were "gaps in the records" that would hamper plaintiffs in determining class membership. *Id*. As long as plaintiffs identify records, along with reliable affidavits, that could be pieced together to perform the tasks required by Rule 23, plaintiffs "establish a 'reliable and administratively feasible mechanism' for determining class membership." *Id.* at 480 (internal quotations and citations omitted); *accord In re Marriott Int'l, Inc. v. Customer Data Sec. Breach Litig. Consumer Actions*, 2022 WL 1396522 (D. Md. May 3, 2022). Plaintiffs have done this here, identifying a wealth of pharmaceutical transactions records (e.g., pharmacy records, PBM records, consumer purchase records) that exist and objectively permit the identification of class members.[105]

Defendants' related contention that Plaintiffs must, at this stage, combine all available data sources into some sort of single mega-database simply to allow identification of class membership, (*see* Defs.' Br. at 71-74), is faulty. The Third Circuit does not require this and, in fact, has said the exact opposite: "Plaintiff need not, at the class certification stage, demonstrate that a single record, or set of records, conclusively establishes class membership." *City Select*, 867 F.3d at 441-42; *see, e.g.*, *Hargrove*, 974 F.3d at 470 (sufficient that "thousands of pages of contracts, driver rosters, security gate logs, and pay statements, as well as testimony from a dozen class members," plus affidavits, existed). Defendants' own expert, Mr. Timothy Kosty, testified [redacted]

[105] ECF 1748-2 ("Craft Decl.") at ¶ 9.
[106] Ex. 249 (Kosty Tr.) at 122:2-6, 132:24-134:15, 220:13-229:11, 238:7-13, 246:13-249:12.
[107] Ex. 249 (Kosty Tr.) at 122:2-6, 132:24-134:15, 220:13-229:11, 238:7-13

[redacted][108] Mr. Kosty could not [redacted] *Id.* Finally, discussion about "combining" data is largely academic; combining data reduces the likelihood of duplicate entries. But in the context of ascertainability, the risk of duplicate entries across multiple data sources is *helpful*, not disabling. As Mr. Kosty readily admits, [redacted].[109]

Defendants' only other critique is that it might be difficult to exclude defendants' employees. Not only is an employee-exclusion commonplace[110] and turns on obviously objective records, but the method underlying Mr. Kosty's criticism here is deeply flawed.[111] Even in the absence of some records (at which Defendants only hint), surely Defendants' employees can be trusted not to falsely sign, e.g., a simple affidavit in connection with a claim, or at worst, only Defendants' officers and directors can be excluded (but not employees).

G. <u>Wholesaler Defendants' Redundant Arguments Lack Merit</u>

Plaintiffs only seek to certify unjust enrichment claims against Wholesaler Defendants. Wholesaler Defendants' stand-alone brief largely repeats the same faulty arguments asserted in all Defendants' main brief. To wit, Wholesaler Defendants' critiques over Plaintiffs' and Dr. Conti's

[108] Ex. 249 (Kosty Tr.) at 219:16-22; 222:9-13, 222:14-18, 238:15-244:18, 250:18-254:10, 267:8-21, 269:9-271:5, 250:8-16.
[109] *Id.* at 250:8-16. This is not an issue for damages because Dr. Conti uses actual, real-world IQVIA data to estimate classwide damages.
[110] *See, e.g.*, *Riaubia v. Hyundai Motor Am.*, 2019 WL 3714497, at *2 (E.D. Pa. Aug. 7, 2019) (excluding "Defendants' affiliates, employees, suppliers, officers, and directors, attorneys, agents, insurers, and dealers . . .").
[111] The flaws in Mr. Kosty's analysis are more fully discussed in the Plaintiffs *Daubert* motion. ECF 2048.

estimation of unjust enrichment damages (Wholesaler Br.at 20) are the same as those discussed above about whose burden (Defendants') it is to show costs, which again is itself a common question. *See supra* Part II.D.5. Their nitpicks over purported state-law variations in unjust enrichment elements (Wholesaler Br. at 12-16) track those in Defendants' main brief. None of Defendants' quibbles have merit or prevent class certification. *See supra* Part II.E. And for every case Wholesalers cite where an unjust enrichment class was not certified (almost exclusively involving laws of all fifty states unlike here, or facts very different than those here), Plaintiffs can cite two more that *did* certify multi-state unjust enrichment classes.[112]

As to Wholesalers' "tracing" issues (Wholesaler Br. at 7-9), Wholesaler Defendants' criticisms ring hollow because (i) to complete Defendant Fact Sheets, they were able to identify whether they merchanted some of the VCDs at issue, (ii) they concede at least some of them maintain some lot level data to track the VCDs they merchanted that were ultimately dispensed to certain customers,[113] and (iii) to the extent a given pharmacy *only* purchased a given VCD (by NDC number) from a Wholesaler Defendant, a jury is entitled to make the reasonable inference that that Wholesaler merchanted the VCD ultimately dispensed.[114] Wholesaler Defendants also ignore that they are obligated under the Drug Supply Chain Security Act ("DSCSA") to maintain detailed transactional data that can be used to trace movements of drugs against Retail Pharmacy Defendants' inventory turnover (i.e., when shipments were made from Wholesalers to Retail

[112] *See, e.g.*, *Sharma v. Gupta*, 2022 WL 970544, at *5 (D.N.J. Mar. 31, 2022) (finding that "no real conflict" exists between New Jersey and Illinois unjust enrichment claims); *In re Checking Account Overdraft Litig.*, 307 F.R.D. 656 (S.D. Fla. 2015) (finding that unjust enrichment "is well-suited for multi-state class treatment by virtue of its uniform availability and focus on the defendant's ill-gotten gains").

[113] ECF 1748-2 (Craft Decl.) at ¶ 44.

[114] *See, e.g.*, Ex. 262 ([redacted]).

Pharmacy Defendants, and how quickly the latter would deplete that delivery). This is especially true for direct-shipped product that went from Wholesalers to specific brick-and-mortar Retail Pharmacy Defendants' stores. Ultimately "tracing" is a common issue to the entire class that can be upheld, or claims can be pared down, at summary judgment or otherwise prior to trial.[115]

More fundamentally, all of these fact and legal questions—*viz.*, which class members received which VCDs that were merchanted by which Wholesaler Defendants, against whom they may assert claims—are predominant common questions, all of which turn on the exact same facts (i.e., Defendants' own transactional records) and same questions of law that would be raised at summary judgment in each and every individual trial were certification denied.

III. CONCLUSION

For the reasons expressed in Plaintiffs' opening brief, as well as those above, The Court should: (a) certify the Classes pursuant to Fed. R. Civ. P. 23(a) and (b)(3) cited in **Ex. 274;** (b) appoint Ruben Honik, Conlee S. Whiteley, and John R. Davis as Class Counsel pursuant to Fed. R. Civ. P. 23(g); and (c) appoint the Named Plaintiffs as found in **Ex. 274** to serve as the Consumer EL Class Representatives.

Dated: May 10, 2022

Respectfully submitted,

/s/ *Ruben Honik*
Ruben Honik
HONIK LLC
1515 Market Street, Suite 1100
Philadelphia, PA 19102
Phone: (267) 435-1300
ruben@honiklaw.com

/s/ *John R. Davis*

/s/ *Conlee S. Whiteley*
Conlee S. Whiteley
David J. Stanoch
KANNER & WHITELEY, LLC
701 Camp Street
New Orleans, LA 70130
Phone: (504)-524-5777
c.whiteley@kanner-law.com

[115] *See, e.g.*, *Olean Wholesale Grocery Coop., Inc. v. Bumble Bee Foods LLC*, 31 F.4th 651, 68-81 (9th Cir. 2022) (en banc) (affirming certification over same standing and damages arguments Wholesaler Defendants make here).

John R. Davis
SLACK DAVIS SANGER, LLP
6001 Bold Ruler Way, Suite 100
Austin, TX 78746
Phone: 512-795-8686
jdavis@slackdavis.com

Proposed Consumer Economic Loss Co-Lead Class Counsel

/s/ Ruben Honik
Ruben Honik
HONIK LLC
1515 Market Street, Suite 1100
Philadelphia, PA 19102
Phone: (267) 435-1300
ruben@honiklaw.com

/s/ Daniel Nigh
Daniel Nigh
LEVIN, PAPANTONIO, THOMAS, MITCHELL RAFFERTY & PROCTOR, P.A.
316 South Baylen Street
Pensacola, FL 32502
Phone: (850) 435-7013
dnigh@levinlaw.com

/s/ Adam Slater
Adam Slater
MAZIE, SLATER, KATZ & FREEMAN, LLC
103 Eisenhower Pkwy, 2nd Flr.
Roseland, NJ 07068
Phone: (973) 228-9898
aslater@mazieslater.com

/s/ Conlee S. Whiteley
Conlee S. Whiteley
KANNER & WHITELEY, LLC
701 Camp Street
New Orleans, LA 70130
Phone: (504)-524-5777
c.whiteley@kanner-law.com

MDL Plaintiffs' Co-Lead Counsel

CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of May, 2022, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system. In addition, I certify that unredacted versions of the foregoing will be served contemporaneously upon liaison counsel for Defendants as well as the Court.

/s/ David J. Stanoch
David J. Stanoch